No. 17-1229

IN THE

# Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

*Petitioner,*

*v.*

TEVA PHARMACEUTICALS USA, INC. AND TEVA PHARMACEUTICAL INDUSTRIES, LTD.,

*Respondents.*

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

## BRIEF OF *AMICUS CURIAE* US INVENTOR, INC. IN SUPPORT OF PETITIONER HELSINN HEALTHCARE S.A.

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## I. Interests of *Amicus Curiae* US Inventor, Inc.[1]

US Inventor, Inc. ("US Inventor") is a non-profit association of inventors devoted to protecting the intellectual property of individuals and small companies. It represents its 13,000 inventor and business members by promoting strong intellectual property rights and a predictable U.S. patent system through education, advocacy, and reform.

US Inventor was founded to support the innovation efforts of the "little guy" inventors, seeking to ensure that strong patent rights are available to support their efforts to develop their inventions, bring those inventions to a point where they can be commercialized, create jobs and industries, and promote continued innovation. Its members consist of individual inventors and small- to medium-sized enterprises that depend heavily on the value created by meaningful patent rights. Their broad experience with the patent system, new technologies, and creating companies, gives them a unique perspective on the important issues presented in this appeal.

## II. Summary of the Argument

The Federal Circuit has decided an important question of law in a way that conflicts with the plain

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1. Pursuant to Supreme Court Rule 37, amicus US Inventor certifies as follows: All parties to this matter have provided written consent to the filing of this amicus curiae brief. No counsel for a party authored this brief in whole or in part, and no party or counsel for a party made a monetary contribution intended to fund preparing or submitting this brief. No person or entity, other than amicus, its members, or its counsel, contributed money intended to fund preparing or submitting this brief.

language of § 102(a)(1) of the America Invents Act ("AIA"), conflicts with the legislative history and purpose of the changed statutory language, conflicts with the USPTO's interpretation of the statute, conflicts with the established canons of statutory construction, conflicts with sound policy, and is otherwise unsupported. New AIA § 102(a)(1) should have been construed as a whole, based on its clear and unequivocal text, to require that "on sale" prior art must be "available to the public." The Federal Circuit did not do that.

The Federal Circuit's *Helsinn* opinion has thrown the "bath water" in with the "baby," importing pre-AIA case law into new AIA § 102(a)(1), despite the inconsistency of that case law with the plain language of the new statute. The *Helsinn* court's interpretation of § 102(a)(1) also newly encompasses foreign "secret sales" as invalidating prior art for the first time in history. Further, the Federal Circuit has created new law, announcing an "existence of sale" prior art bar, which is not supported by either the language of the new statute or its legislative history.

This brief seeks to address aspects of this erroneous and detrimental opinion in addition to those pointed out in Petitioner's brief, in an effort to assist the Court in its consideration of the important issues at stake. If allowed to stand, the *Helsinn* opinion will have a severe and disproportionate impact on the small U.S. inventor—the life and blood of our economy—whose interests our patent law system is supposed to foster and protect.

Small inventors often lack the resources or manufacturing ability to develop their inventions themselves. They rely on development arrangements

and seed funding to pay for the significant costs of patent prosecution and of engaging in further experimentation, discovery, and invention development. They need to be able to rely on their intellectual property rights as a basis for attracting businesses that may be interested in those innovations, and in partnering, collaborating, or investing in them. To do that, they must be allowed to confidentially disclose the nature of those inventions without jeopardizing their patent rights, and include those rights in confidential transactions. The "secret sale" trap for the unwary small inventor jeopardizes their all-important patent rights.

The plain text of AIA § 102(a)(1) requires that the claimed invention must be available to the public in order for the on sale bar to apply, and thus does not encompass secret sales. Moreover, even if the statute were ambiguous, the legislative history consistently confirms this construction.

Over time, different approaches to statutory construction have waxed and waned. This case, however, is non-tide-sensitive. Both the plain language of the statute and the legislative history cohesively require that in order for a sale to qualify as invalidating prior art, it must make the claimed invention available to the public.

The Federal Circuit also accorded the wrong rank to the available legislative history. The Federal Circuit ignored both the Senate Committee Report, which adopted the statutory language at issue, and the House Committee Report, which embraced that language and explained the policies behind it. The court instead focused on floor statements, impugning their reliability

with regard to determining Congress's intent. Moreover, contrary to the Federal Circuit's criticism of the floor statements as "after the fact," the Committee Reports explained the reasoning behind and the meaning of the statutory language before votes were taken.

A fair construction should be adopted here. Nothing in the plain statutory text, nor in the legislative history, nor in any case law of this Court since the *Pennock* days,[2] would support construing the new statute to invalidate U.S. patents based on "secret sales" (now including secret foreign sales), which do not make the claimed invention available to the public. Such a construction should not be adopted.

Teva has taken the position that "on sale" should keep its "historical" meaning. Words and phrases, however, must be read and construed in the context of the complete statutory provision in which they appear. The statute must be read as a whole. This is particularly important here, where the statute itself is comparatively short, and both the wording and the punctuation of this statute were purposely changed. The statute as a whole evidences that Congress intended the statute to have a different meaning.

The Federal Circuit indicated that its finding that the "on sale" bar applied was limited to the "particular Supply and Purchase Agreement" before it. That finding, however, necessarily turned on the court's conclusion that "if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale" in order for the "on sale" bar to apply. *Helsinn*

2. *Pennock v. Dialogue*, 27 U.S. 1 (1829).

*Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356, 1371 (Fed. Cir. 2017). That broad construction of the "on sale" bar is directly contrary to the plain meaning of 35 U.S.C. § 102(a)(1), contrary to its purpose, contrary to its legislative history, and would defeat the efforts of the House and the Senate to harmonize the U.S. view of what counts as prior art with the views of the rest of the world.

All of the foregoing considerations point to a construction under which "secret sales" are not invalidating prior art under post-AIA § 102(a)(1). Under post-AIA § 102(a)(1), "prior art" cannot be invalidating prior art unless it made the claimed invention available to the public.

## III. Argument

### A. The Federal Circuit's Interpretation of Section 102(a)(1) Is Contrary to the Purpose of the AIA and Destroys Harmony with Foreign Law.

As Petitioner notes in its merits brief, a key consideration underlying enactment of the AIA was the conversion of the American patent system from a "first-to-invent" to a "first-inventor-to-file" system, thereby taking a major step towards harmonizing the American patent system with the systems of other leading industrialized countries around the world. *See* Brief for the Petitioner (Aug. 23, 2018) ("Pet. Br.") at 5-6. Congress recognized that it is "common for inventors and companies to file for protection in several countries at the same time." H.R. Rep. No. 112–98, 112th Cong., 1st Sess. (June 1, 2011) ("AIA Committee Report") at 41. An important goal of international harmonization was to eliminate the need

for patent applicants to comply with multiple incompatible patent systems.

As part of that harmonization, Congress redefined the scope of invalidating prior art under § 102 as follows:

> A person shall be entitled to a patent unless—(1) the claimed invention was patented, described in a printed publication, *or* in public use, on sale, *or otherwise available to the public* before the effective filing date of the claimed invention ....

AIA 35 U.S.C. § 102(a)(1) (emphasis added).[3]

A primary purpose of the "on-sale" bar is to "exclude from consideration for patent protection knowledge that is *already available to the public*" on the grounds that "the creation of a monopoly in such information would not only serve no socially useful purpose, but would in fact injure the public by *removing* existing knowledge from public use." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 148 (1989) (emphasis added). By enacting the AIA and making explicit the requirement that prior art make the claimed invention available to the public to qualify as potentially invalidating prior art, Congress affirmed that longstanding purpose.

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3. The redefinition of the scope of prior art is only one of the significant changes wrought by the AIA. For a comprehensive list of those changes, see R.A. Armitage, *Understanding the America Invents Act and Its Implications for Patenting*, 40 AIPLA Q. J. 1, 10-14 (2012).

Construing AIA § 102(a)(1) as excluding as prior art sales that have not made the invention "available to the public" also comports with the AIA's overarching goal of "harmonizing our system for granting patents with the best parts of other major patent systems throughout the industrialized world." AIA Committee Report at 39. No other major industrialized nation defines invalidating prior art as encompassing secret sales. *See, e.g.*, Brief for The Naples Roundtable, Inc. as Amicus Curiae Supporting Plaintiffs-Appellees, *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356 (Fed. Cir. 2017) (Nos. 2016-1284, 2016-1287), at 6-13. Interpreting the on-sale bar to encompass secret sales would undermine Congress's goal of ensuring that what counts as prior art under American law is consistent with prior art recognized by other nations.

Before the AIA was enacted, an invention that was "in public use" or "on sale" precluded the grant of a patent only if such public use or sale occurred "in this country." Pre-AIA 35 U.S.C. § 102(b). Prior art now encompasses "all art that *publicly exists* prior to the filing date" regardless of geographical location. AIA Committee Report at 42 (emphasis added). This geographical expansion is interconnected with the limitation of prior art to the categories of *publicly available* materials listed in § 102(a)(1), including those "in public use" or "on sale." Both the geographical expansion and the restriction of prior art to publicly available materials harmonize U.S. law with foreign law regarding the bases for invalidity. The Federal Circuit opinion, which did not address either the AIA Committee Report for the enacted version of the AIA, or the previous Senate Judiciary Committee Report which proposed and explained the language at issue,

utterly defeats a major purpose of Congress in enacting § 102(a)(1), and would put the United States, once again, out of step with the rest of the world.

### B. The "Little Guy" Stands to Bear a Disproportionate and the Most Destructive Brunt of this "On Sale" Bar Storm.

The small inventor is the true representative of the culture of innovation and ingenuity that Article I, Section 8, Clause 8 of the Constitution was meant to promote and foster. The Federal Circuit's *Helsinn* opinion effects a direct hit on this country's grassroots inventive ethos by disincentivizing the risk-taking and experimentation that are inherent in the inventive process, and creating uncertainty with respect to development and commercialization of inventions.[4]

The *Helsinn* opinion is especially problematic because it comes at a time when the United States is facing a true crisis in innovation. Countries that were once net importers of advances in technology are now eclipsing the United States with respect to advances in the industries of the future. For example, in 2017, China accounted for 48% of the world's total artificial intelligence startup funding, while the United States accounted for only 38%.[5] China

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4. *See generally* P. Morinville, "Crisis in American Innovation," US Inventor, *available at* http://www.usinventor.org/wp-content/uploads/2017/08/USI-Crisis-in-American-Innovation-Full-Version.pdf.

5. *See* J. Vincent, "China overtakes US in AI startup funding with a focus on facial recognition and chips," at 1, *available at* https://www.theverge.com/2018/2/22/17039696/china-us-ai-funding-startup-comparison.

is either already leading or is becoming the world leader in quantum computing, solar cells, and other technologies that provide the foundation for several important industries, including advanced energy production and globalized currencies.[6] These changes are reflected in the significant difference in the number of patent applications between the two countries: by 2015 nearly twice as many patent applications were filed in China (1,101,864) as were filed in the United States (589,410).[7] In the first quarter of 2017, the number of angel and seed stage funding rounds in the United States dropped by 62 percent.[8] Entrepreneurs have found it harder and harder to raise money through venture capital.[9]

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6. *See* J. Pekkanen, "China Leads the Quantum Race While the West Plays Catch Up," at 2, *available at* https://www.forbes.com/sites/saadiampekkanen/2016/09/30/china-leads-the-quantum-race-while-the-west-plays-catchup/#b14212592856; M. Meng, "With high-performance cells, China takes aim at high-end solar market," *available at* https://www.reuters.com/article/us-china-solar-cost-analysis/with-high-performance-cells-china-takes-aim-at-high-end-solar-market-idUSKCN1BP0X6.

7. WIPO, "Global Patent Applications Rose to 2.9 Million in 2015 on Strong Growth from China; Demand Also Increased for Other Intellectual Property Rights," at 1, *available at* http://www.wipo.int/pressroom/en/articles/2016/article_0017.html.

8. *See* M. Kendall, "Silicon Valley investing slump continues, fewer startups get funded," at 4, *available at* https://www.siliconvalley.com/2017/04/04/silicon-valley-investing-slump-continues-fewer-startups-get-funded/.

9. *Id.*

Indeed, some ninety percent of all startups in the United States fail,[10] and lack of funding is consistently cited as a significant cause of that failure.[11] Lack of patent protection is, in turn, a major contributor to the inability to get funding.[12] Scholars from the Harvard Business School, New York University's Stern School of Business, and the National Bureau of Economic Research recently undertook a study of the incremental value of patents to startups in the United States.[13] The authors define the incremental value of a patent as "the incremental return generated by the patent, beyond what could be earned if the invention were not granted a patent."[14]

The researchers concluded that obtaining patent protection has a dramatic effect on a startup's likelihood of success. They estimated that "[f]or the average startup in our sample, . . . receiving a patent leads to 16 additional

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10. T. Clark, "Why do so many startups fail?" Forbes Magazine (March 19, 2015) available at https://www.forbes.com/sites/sap/2015/05/19/why-do-so-many-start-ups-fail/#18b823755873.

11. V. Lance, "Top 20 Reasons Why Startups Fail," Forbes Magazine (March 2, 2015) available at https://www.forbes.com/sites/groupthink/2016/03/02/top-20-reasons-why-startups-fail-infographic/#5502dc823911.

12. T. Clark, "Why do so many startups fail?" available at https://www.forbes.com/sites/sap/2015/05/19/why-do-so-many-start-ups-fail/#18b823755873.

13. S. Farre-Mensa, et al., "What Is a Patent Worth? Evidence from the U.S. Patent 'Lottery'" (March 14, 2017), USPTO Economic Working Paper 2015-5, available at SSRN: https://ssrn.com/abstract=2704028 or http://dx.doi.org/10.2139/ssrn.2704028.

14. *Id.* at 1-2.

employees after five years, and $10.6 million in additional sales cumulated over five years. . . ." *Id.* at 4. They further concluded that:

> [a] first patent grant also increases both the number of subsequent patents the firm is granted (by 49%) and their quality (with the average number of citations per subsequent patent increasing by 26%). Patent approvals appear to have a particularly strong effect on sales growth and follow-on innovation for startups in the IT sector—a result that contrasts with prior survey evidence that large IT firms consider patents to be among the least effective mechanisms to ensure the profitability of their R&D investments.

*Id.* (internal citation omitted).

The researchers explained that these dramatic effects are, in turn, attributable to one critical factor—patent protection. A patent grant means the startup's chances of getting funding grow substantially:

> We find that a patent grant increases a startup's chances of securing funding from [venture capital] by 47%, and of securing a loan by pledging the patent as collateral by 76%, within three years of the patent decision. A patent grant also more than doubles the odds of the startup raising funding from public investors through an IPO. . . . [P]atent grants facilitate startups' access to external finance in contexts where information frictions, and thus

> contractual hazards, are high. A patent grant sets a startup on a growth path through funding that helps transform its ideas into products and services that generate jobs, revenues, and follow-on inventions.

*Id.*

Other research has led to similar findings. With regard to start-up biopharmaceutical innovation, for example, "[p]atents play an essential role in the economic 'ecosystem' of discovery and investment. . . ." H. Grabowski, et al., ***The Role of Patents and Research and Development Incentives in Biopharmaceutical Innovation***, Intellectual Prop. & Innov. (Feb. 2015). Moreover, "the strength of intellectual property protection plays a key role in funding and partnership opportunities for such firms." *Id.*

Small inventors might not be able to develop their intellectual property from nascent conception to a fully developed product that can contribute to society without funding and assistance from a partner in the pertinent industry. Further, they might not be able to develop their intellectual property itself, and pursue protection of it, without partners. Similarly, as in *Helsinn*, the invention at issue might have enormous promise, but there may be multiple different embodiments of the invention, and research and development resources may be necessary to develop and define the invention.

If allowed to stand, the Federal Circuit's opinion in *Helsinn* will cause significant irreparable harm to small inventors, including by making it much harder for them to get their inventions patented, and get the funding they

need to develop their inventions and bring them to market. This, in turn, will have negative consequences for our economic well-being as a whole, because small inventors are critical to the innovation ecosystem. As of about a decade ago, small businesses hired 43 percent of America's high tech workers (e.g., scientists, engineers, computer programmers), produced 16.5 times more patents per employee than large patenting firms, generated 65 percent of net new jobs over the previous 17 years, and made up 97.5 percent of all identified U.S. exporters.[15]

Confidential inclusion of patent rights as part of a transaction is an essential step in enabling a small inventor to bring an invention from its conception to the point where it becomes a contribution to society. Trial and error are inherent in the innovation process, and significant work may only yield a small amount of patentable and commercially viable matter. If inventors cannot disclose their inventions under confidentiality agreements as part of their business development transactions without fear that they are thereby placing the patentability of those inventions in jeopardy, future innovation, collaboration, and development will be severely chilled.

This is especially true when inventions are being developed by smaller companies, where an agreement with another company to fund or share the costs of development may rise to the level of materiality under Security and Exchange Commission ("SEC") laws, and thus obligate such companies to disclose the agreement

15. Small Business Administration, Office of Advocacy: The Voice of Small Business in Government (updated Jan. 2011), *available at* https://www.sba.gov/sites/default/files/sbfaq.pdf.

in their public filings. *See* 17 C.F.R. § 240.12b-2 (SEC defining "material" as those matters to which there is a substantial likelihood that a reasonable investor would attach importance in determining whether to buy or sell the securities registered). This means that the materiality threshold for including information in the SEC filings of a million-dollar company is far lower than it is for a billion-dollar company—small businesses have to disclose much smaller transactions to comply with the SEC's materiality requirement than large businesses do. Small businesses also will face difficulty in attracting and co-developing or acquiring rights to inventive ideas for development and public benefit.

In the pharmaceutical industry, drug development typically requires many years and billions of dollars.[16] In order for smaller companies to participate in the drug development process, they necessarily must partner with larger companies or venture capital funding sources. If a conveyance of rights under the invention is included as part of the collaboration agreement such that it qualifies as a "sale," *Helsinn* would render that agreement invalidating prior art, even if the invention itself is not disclosed to, or otherwise put in the hands of, the public.

The Federal Circuit also injected uncertainty and unpredictability into a judicially created "existence of sale" bar by making statements such as, "We do not find that distribution agreements will always be invalidating

16. *See* Tufts Center for the Study of Drug Development (CSDD), "Tufts CSDD Assessment of Cost to Develop and Win Marketing Approval for a New Drug Now Published," *available at* http://csdd.tufts.edu/news/complete_story/tufts_csdd_rd_cost_study_now_published.

under § 102(b). We simply find that this particular Supply and Purchase Agreement is." *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, 855 F.3d 1356, 1371 (Fed. Cir. 2017). That particular Supply and Purchase Agreement, however, was redacted, and did not disclose the claimed invention. *Helsinn*, 855 F.3d at 1361-62.

The Federal Circuit has created a Hobson's choice for the small inventor, both alternatives of which are detrimental to innovation and against the public interest: collaborate and develop your invention but give up your patent rights by doing so (thus killing the invention, and keeping the public from benefiting from it in the process), or patent it but do not enter into the agreements necessary to develop it, and thus leave it and the patent sitting on a shelf (thus killing the invention, and keeping the public from benefiting from it in the process).

The Federal Circuit's interpretation of the scope of prior art also inherently creates uncertainty because it includes patent-defeating secret sales that may have taken place anywhere in the world. That interpretation makes investing in innovation much riskier and therefore much more costly. The ability to ascertain what exists as invalidating prior art is of critical importance in our patent system. All participants in the patent system—inventors trying to develop their inventions and seeking partners to do so, companies deciding to enforce their own patents or to license or acquire patents from others, and investors valuing the patent portfolios of potential investment targets—must be able to determine what constitutes potentially invalidating prior art under the AIA. An explicit objective of the AIA was to "establish a more efficient and streamlined patent system that

will improve patent quality and limit unnecessary and counterproductive litigation costs." AIA Committee Report at 40.

Encompassing worldwide "secret sales" grossly and unsupportably expands what qualifies as prior art under the AIA, and thus greatly increases uncertainty and unreliability, rather than effecting the streamlining that was one of the AIA's overarching goals. The ability to ascertain what prior art exists informs participants' decisions about how best to invest their resources, and whether or not to invest in innovation. Encompassing "secret sales" within the scope of § 102(a)(1) undermines such efforts.

Small inventors face numerous challenges and obstacles these days, and a dependable and clear patent protection framework is an essential foundation for them to be able to survive and thrive. They need this Court to reverse the *Helsinn* opinion, before it and its progeny cause irreparable damage.

### C. The Federal Circuit's Opinion Is Contrary to the Plain Language of the Statute.

"As with any question of statutory interpretation, [the Court's] analysis begins with the plain language of the statute." *Jimenez v. Quarterman*, 555 U.S. 113, 118 (2009) (citation omitted). It is well settled that when interpreting a statute, one must begin with "the assumption that the ordinary meaning of the language chosen by Congress accurately expresses the legislative purpose." *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 101 (2011) (internal quotation marks, modification, and citation omitted).

A "cardinal rule" of statutory construction is "that a statute is to be read as a whole." *Corley v. United States*, 556 U.S. 303, 314 n.5 (2009) (emphasis added) (quoting *King v. St. Vincent's Hospital*, 502 U.S. 215, 221 (1991)); *see also Samantar v. Yousuf*, 560 U.S. 305, 319 (2010) ("[W]e do not . . . construe statutory phrases in isolation; we read statutes as a whole." (quoting *United States v. Morton*, 467 U.S. 822, 828 (1984))). Here, the meaning of "on sale" must be construed in the context of the language of new AIA § 102(a)(1) as a whole.[17] The ordinary meaning of § 102(a)(1) of the AIA requires that a sale of a claimed invention make the "claimed invention" "available to the public" in order for the sale to qualify as invalidating prior art. "Patented," "described in a printed publication," "public use," and "on sale" are all specific circumstances in which the "claimed invention" can be made "available to the public." The catchall category, "or otherwise available to the public," coming as it does at the end of the list of those prior art categories, then encompasses other ways in which the invention can be made "available to the public," and confirms that the terms preceding it—including the term "on sale"—also involve making the invention "available to the public."

Webster's Third New International Dictionary defines "otherwise" as "in a different way or another manner." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1598 (2002). In order for a claimed invention to become "available to the public" in a "different way or manner,"

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17. Instead of focusing on the language of the new statute as a whole, in its Brief in Opposition to Certiorari ("Opp. Br."), Teva did the opposite, and attempted to import what it characterizes as the "historical" meaning of "on sale" as encompassing "secret sales." *See* Opp. Br. at 1.

there must be a referenced "way or manner" in which the invention is "available to the public."

In plain English, "or otherwise available to the public" means "or *in other ways* available to the public." The use of the "or otherwise" clause thus linguistically signals that the "on sale" activity—like the other activities enumerated in the provision—must make the claimed invention "available to the public." This Court made a similar observation in *United States v. Standard Brewery, Inc.*, 251 U.S. 210, 217-18 (1920), rejecting the government's position that a statute prohibiting products for making "beer, wine, or other intoxicating malt or vinous liquor for beverage purposes" encompassed "beer and wine whether intoxicating or not," and concluding that the provision aimed "only at intoxicating beverages." Any other interpretation of the statutory text would ignore or render superfluous the term "or otherwise."

A contrary interpretation also would ignore the term "available to the public." Requiring that the claimed invention be "available to the public" necessarily requires that the public have access to the claimed invention. Indeed, as Congressman Smith, one of the AIA's sponsors, explained in his amicus brief:

> The changes to the law arising from the drafting of new § 102's "prior art" provision involved retiring the phrase "known or used" from repealed § 102(a)'s definition of prior art, *notwithstanding that this phrase had been used to define "prior art" in every patent statute since 1790.* It was replaced with an alter ego term, "available to the public."

> This new terminology is used internationally to define prior art, in part by excluding confidential or otherwise secret subject matter from qualifying as prior art.

Brief for Amicus Curiae Congressman Lamar Smith in Support of Petitioner, *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc., et al.*, (No. 17-1229) (Aug. 23, 2018) at 2 (emphasis added).[18]

Ignoring "otherwise" and "available to the public" violates "one of the most basic interpretive canons—that a statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." *Corley v. United States*, 556 U.S. 303, 314 (2009) (internal quotation marks, modification, and citation omitted). Indeed, this Court has long recognized that it is "not at liberty to construe any statute so as to deny effect to any part of its language." *Market Co. v. Hoffman*, 101 U.S. 112, 115-16 (1879). The "or otherwise" and "available to the public" language is in the statute for a reason. The *Helsinn* opinion effectively erases that language from the statute.

Interpreting "on sale" to encompass secret sales would also be contrary to the most natural reading of the text. There is no dispute that the first three categories of prior art listed in § 102(a)(1)—inventions that are "patented," "described in printed publications," or "in public use"—

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18. The fact that one of the actual sponsors of the AIA has filed several amicus briefs on the issue is notable; it is not often that the Court has the opportunity for such direct insight into a statute's legislative history.

describe prior art that is publicly accessible. "In public use" and "on sale" both follow the ", or" that Congress added after "printed publication"—which deliberately set off the language: "or in public use, on sale, or otherwise available to the public." Given that the penultimate category of prior art—inventions that are "on sale"—is followed by the catchall category, "or otherwise available to the public," it stands to reason that, like the three preceding categories of prior art, and like the subsequent catchall category, sales also have to make the invention publicly accessible in order to qualify as potentially invalidating prior art. The statute was written so that all five categories share the commonality of being "available to the public."

The most natural and only reasonable interpretation of the language that Congress chose is that the "claimed invention" that is "on sale" must be "available to the public" in order for the "sale" to be invalidating prior art. The term "otherwise" and the comma before the phrase "or otherwise available to the public" do not leave room for any other reasonable interpretation.

### D. The Federal Circuit's Opinion Is Contrary to the Legislative History of § 102(a).

If a statute is perceived to be ambiguous, the legislative history of that statute should be considered. Here, the Federal Circuit did not appropriately do that. The Federal Circuit did not accord the available legislative history the right rank in the hierarchy of materials available for consideration in its statutory analysis. Here, the Federal Circuit disregarded the insights available through the highest ranking available legislative history: the Committee Reports.

The House Committee Report accompanying the AIA could hardly be clearer that Congress intended to redefine the scope of invalidating prior art to exclude art that was not publicly available: "[p]rior art will be measured from the filing date of the application and will typically include all art that *publicly exists* prior to the filing date, other than disclosures by the inventor within 1 year of filing." AIA Committee Report at 42 (emphasis added). The Report explains: "Thus, in section 102 the 'in this country' limitation as applied to 'public use' and 'on sale' is removed, and the phrase 'available to the public' is added to clarify the broad scope of relevant prior art, as well as to *emphasize the fact that it must be publicly available*." *Id.* at 42-43 (emphasis added); *see also* S. Rep. No. 111-18, 111th Cong., 1st Sess. at 6 (May 12, 2009). It is remarkable that the Federal Circuit never considered or mentioned either the Senate Judiciary Committee Report, which was the source of the language at issue, or the House AIA Committee Report.

The Court has recognized that statements in Committee Reports are "the authoritative source for finding the Legislature's intent" because "the Committee Reports on the bill . . . represent the considered and collective understanding of those [members of Congress] involved in drafting and studying proposed legislation." *Eldred v. Ashcroft*, 537 U.S. 186, 209 n.16 (2003) (quoting *Garcia v. United States*, 469 U.S. 70, 76 (1984)) (internal quotation marks omitted). "[T]hese materials 'have long been important means of informing the whole chamber about proposed legislation,' . . . a point Members [of Congress] themselves have emphasized over the years. It is thus no surprise that legislative staffers view committee and conference reports as the most reliable type of

legislative history." *Digital Realty Tr., Inc. v. Somers*, 138 S. Ct. 767, 782-83 (2018) (Sotomayor, J., concurring) (quoting A. Gluck, et al., *Statutory Interpretation from the Inside—An Empirical Study of Congressional Drafting, Delegation and the Canons: Part I*, 65 Stan. L. Rev. 901, 977 (2013)).

The theme of public availability was reiterated by Senator Kyl on March 8, 2011, when he explained that Congress chose the word "otherwise" to "make[] clear that the preceding clauses describe things that are of the same quality or nature as the final clause—that is, although different categories of prior art are listed, all of them are limited to that which makes the invention 'available to the public.'" 157 Cong. Rec. S1368, S1370 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl) (cited in final Committee Report, H.R. Rep. No. 112-98, at 43 n.20 (June 1, 2011)). In a hearing on the final bill on September 8, 2011, Senator Kyl again observed:

> As Chairman Smith most recently explained in his June 22 remarks, "contrary to current precedent, in order to trigger the bar in new 102(a) in our legislation, an action must make the patented subject matter 'available to the public' before the effective filing date." . . . When the committee included the words "or otherwise available to the public" in section 102(a), the word "otherwise" made clear that the preceding items are things that are of the same quality or nature. As a result, the preceding events and things are limited to those that make the invention "available to the public."

157 Cong. Rec. S5431 (daily ed. September 8, 2011) (statement of Sen. Kyl) (quoting 157 Cong. Rec. H4429 (daily ed. June 22, 2011) (statement of Rep. Smith, lead sponsor of House AIA bill, H.R. 1249)).

A few years earlier, Senator Kyl had explained that the purpose of "eliminating confidential sales and other secret activities as grounds for invalidity and imposing a general standard of public availability" was to "make the patent system simpler and more transparent," which change, in turn, will "provide greater certainty and predictability—it should also substantially reduce the need for discovery in patent litigation, since defendants will no longer need to uncover evidence of private sales or offers for sale or other nonpublic information in order to determine whether the patent is valid." 154 Cong. Rec. S9992 (daily ed. Sept. 27, 2008) (statement of Sen. Kyl).

Statements in the AIA's legislative history by "the sponsor[s] of the language ultimately enacted, are an authoritative guide to the statute's construction." *See N. Haven Bd. of Educ. v. Bell*, 456 U.S. 512, 526-27 (1982) (collecting cases); *see also Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 585 (1988) ("It is the sponsors that we look to when the meaning of the statutory words is in doubt."); *Bowsher v. Merck & Co.*, 460 U.S. 824, 831-33 (1983) ("The only explanation in the legislative history of the meaning and purpose of the amendment is that of [a sponsor]. His statement, which, as the explanation of the sponsor of the language, is an 'authoritative guide to the statute's construction. . . .'") (quoting *N. Haven Bd. of Educ.*, 456 U.S. at 527)); *Schwegmann Bros. v. Calvert Distillers Corp.*, 341 U.S. 384, 394-95 (1951).

The Federal Circuit's statement that "floor statements are typically not reliable as indicators of congressional intent," and its citation to *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546 (2005), are inapposite. *See Helsinn*, 855 F.3d at 1368. The legislative history at issue in *Exxon* is not comparable to the relevant legislative history of the AIA. In *Exxon*, Committee Reports conflicted regarding the correct statutory language interpretation at issue. *Id.* at 569-70. Here, all Committee Reports are in agreement with regard to the meaning of the language at issue. Moreover, in *Exxon*, the Court rejected one interpretation where three law professors who had participated in drafting the statute acknowledged in a journal essay that (1) the plain text of the statute was contrary to the rejected interpretation, and (2) the rejected interpretation "in the House Report was a *post hoc* attempt to alter that result." *Id.* Again, no such circumstances exist here, where Petitioner's interpretation follows the plain statutory language, and the legislative history for the AIA consistently supports that interpretation. Indeed, the Court has previously concluded that *Exxon* does not counsel against a party's interpretation where the legislative history supports only one—in this case, Petitioner's—interpretation of the statutory language at issue. *See Mohamad v. Palestinian Auth.*, 566 U.S. 449, 459-60 (2012) (observing that "limitations of th[e] drafting history" did not overcome the fact that "the sole explanation for [the statutory language] . . . confirms what we have concluded from the text alone").

The suggestion that Congress either was not aware of how it was revising the scope of invalidating prior art, or was not aware of the consequences its changes would have, *Helsinn*, 855 F.3d at 1371, is untenable. Congress

intended to revise the scope of invalidating prior art so that it did not encompass secret sales; the language it chose "accurately expresses [its] legislative purpose." *Microsoft*, 564 U.S. at 101.

### E. The Federal Circuit's Opinion Is Contrary to the USPTO Interpretation and Guidelines.

Based on its review of the statutory text and the legislative history, the U.S. Patent and Trademark Office ("USPTO") concluded that the AIA requires that sales under § 102(a)(1) must be publicly available: "[t]he phrase 'on sale' in AIA 35 U.S.C. 102(a)(1) is treated as having the same meaning as 'on sale' in pre-AIA 35 U.S.C. 102(b), *except that the sale must make the invention available to the public.*" Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith America Invents Act, 78 Fed. Reg. 11059, 11075 (Feb. 14, 2013) (emphasis added).

"These examination guidelines indicate that the Office views the 'or otherwise available to the public' residual clause of the AIA's 35 U.S.C. 102(a)(1) as indicating that secret sale or use activity does not qualify as prior art . . . [and] that an activity (such as a sale, offer for sale, or other commercial activity) is secret (non-public) if, for example, it is among individuals having an obligation of confidentiality to the inventor." *Id.* at 11060. The USPTO explained that "[r]esidual clauses such as 'or otherwise' or 'or other' are generally viewed as modifying the preceding phrase or phrases," and that "[t]herefore, the Office views the 'or otherwise available to the public' residual clause of the AIA's 35 U.S.C. 102(a)(1) as indicating that secret sale or use activity does not qualify as prior art." *Id.* at

11062 (citations omitted). It also noted "that the Office's interpretation is consistent with the interpretation that was clearly expressed by the bicameral sponsors of the AIA during the congressional deliberations on the measure." *Id.* (citations omitted). Indeed, in considering the "on sale" language in the context of the "or otherwise available to the public" language, the USPTO's interpretation is in keeping with the "cardinal rule" that the statute is to be "read as a whole."

The USPTO also observed that some commentators said that "interpreting the 'on sale' provision to require public availability is good public policy in that it would lower litigation costs by simplifying discovery, and would reduce unexpected prior art pitfalls for inventors who are not well versed in the law." *Id.*

The USPTO's interpretation not only is the most natural reading of the statute, but also reflects close attention to the statute's legislative history.

### F. The Federal Circuit's Opinion Is Inconsistent with Established Canons of Statutory Construction.

#### 1. Noscitur a Sociis: The "On Sale" Bar Reflects the "Company It Keeps."

Even if § 102 were ambiguous (which it is not), established canons of construction support interpreting the "on sale" bar as requiring that an invalidating sale must make the claimed invention publicly available. As Petitioner notes in its brief, under the noscitur a sociis canon of statutory construction, "words in a statute

are known by the company [they] keep[]." Pet. Br. at 20 (quoting *Gustafson v. Alloyd Co.*, 513 U.S. 561, 575 (1995)).

The rule of noscitur a sociis (or the associated-words canon) "is a rule of construction to be applied where there is doubt and ambiguity concerning the meaning of a word or expression used by the legislative body in enacting a statute." *X-Acto Crescent Prods. Co., Inc. v. United States*, 27 Cust. Ct. 190, 192 (U.S. 1951); *see also Yates v. United States*, 135 S. Ct. 1074, 1085 (2015); *Gutierrez v. Ada*, 528 U.S. 250, 255 (2000); *Gustafson v. Alloyd Co.*, 513 U.S. 561, 575 (1995); *Jarecki v. G. D. Searle & Co.*, 367 U.S. 303, 307 (1961) ("The maxim *noscitur a sociis*, that a word is known by the company it keeps, while not an inescapable rule, is often wisely applied where a word is capable of many meanings in order to avoid the giving of unintended breadth to the Acts of Congress."); *Brown v. Chicago & N. W. R. Co.*, 77 N.W. 748, 752 (Wis. 1899).

For example, a statute saying "signed, or otherwise adopted or approved," was interpreted "by ordinary principles of noscitur a sociis" as meaning "an approval comparable to a signature." *United States v. Begaye*, 236 F.R.D. 448, 451 (D. Ariz. 2006) (discussing *Campbell v. United States*, 296 F.2d 527, 532-33 (1st Cir. 1961)). In *Jarecki*, this Court applied the maxim noscitur a sociis and said that in a statute having three words in conjunction—"exploration, discovery, or prospecting"—the word "discovery" "gathers meaning from the words around it," and because these words describe activity in the oil and gas and mining industries, "discovery" cannot be applied to development and manufacture of drugs and cameras. 367 U.S. at 307.

In accordance with the noscitur a sociis canon, the term "on sale" should be interpreted by association with both its closest neighbors ("in public use" and "otherwise available to the public") and its more distant neighbors ("patented" and "described in a printed publication"), all of which denote public availability.[19]

### 2. The "Last Antecedent" Canon Is Inapplicable.

The "last antecedent" doctrine, referenced in the concurring opinion in the Federal Circuit's order denying en banc review, *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, No. 2016-1284, 2016-1787, slip op. at 7 (Fed. Cir. Jan. 16, 2018) ("Slip op."), is inapplicable here. The last antecedent rule "provides that 'a limiting clause or phrase . . . should ordinarily be read as modifying only the noun or phrase that it immediately follows'" and

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19. Another related canon, the ejusdem generis rule (according to which, in a series of words of description, a general word can be limited to a meaning similar to that of objects of a like kind with the specified terms), further supports commonality of interpretation here. The U.S. Courts of Customs and Patent Appeals applied the ejusdem generis canon to hold that the term "otherwise manufactured" in a provision stating that "[p]earl, mother of, and shells, not sawed, cut, flaked, polished, or otherwise manufactured" was to "take color and meaning from the enumerated operations, which are to be regarded as manufacturing operations within the purview" of this paragraph. *August Bentkamp v. United States*, 40 C.C.P.A. 70, 73, 77 (C.C.P.A. 1952). "To hold differently would be to ignore the plain meaning of the . . . statutory language and *would in effect eliminate and render meaningless the word "otherwise"* in each of the[] paragraphs [at issue]. This is a result which we believe Congress clearly could not have intended." *Id.* at 77 (emphasis added).

"reflects the basic intuition that when a modifier appears at the end of a list, it is easier to apply that modifier only to the item directly before it." *Lockhart v. United States*, 136 S. Ct. 958, 962-63 (2016) (quoting *Barnhart v. Thomas*, 540 U.S. 20, 46 (2003)).

The concurring opinion suggests that "the doctrine implies that 'to the public' limits only 'otherwise available.'" Slip op. at 7. Here, however, "otherwise" modifies "available to the public," not the other way around. Moreover, the "noun or phrase" immediately before "or otherwise available to the public" is "on sale." If anything, application of the "last antecedent rule" would result in "otherwise available to the public" applying to "on sale."

The structure of § 102(a) does not invite application of the "last antecedent rule," because the type of "limiting clause or phrase" that calls for application of this doctrine is not present in the statute. Application of that canon also results in a cramped reading that is true neither to the provision's actual language nor to its legislative history. *Davis* v. *Michigan Dep't of Treasury*, 489 U.S. 803, 809 (1989) ("It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme").

The "last antecedent rule" is not a good linguistic fit, and does not apply here.

### G. Confidentiality Obligations Create a Special Circumstance That This Court Has Long Recognized.

Since the days of *Pennock*[20] and *Egbert*,[21] the Court has recognized that confidentiality obligations to an inventor create a special circumstance.[22] In *Pennock*, the Court recognized public accessibility as a key consideration: "[I]f a man dedicates a way, or other easement to the public, it is supposed to carry with it a permanent right of user." *Pennock*, 27 U.S. at 16. The Court was concerned that there "would be no quid pro quo—no price for the exclusive right or monopoly conferred upon the inventor *if the public were already in possession and common use of an invention*." *See id.* at 23 (emphasis added).

In *Egbert*, the Court stated: "[i]f an inventor, having made his device, gives or sells it to another, to be used by the donee or vendee, *without limitation or restriction, or injunction of secrecy*, and it is so used, such use is pubic, even though the use and knowledge of the use may be confined to one person." *Egbert*, 104 U.S. at 336 (emphasis added). The *Egbert* Court similarly considered a sale of an invention for unrestricted public use—"if [an] inventor *sells* a machine of which his invention forms a part, and *allows it to be used without restriction* of any kind, the use is a public one." *Egbert*, 104 U.S. at 336 (emphasis

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20. *Pennock v. Dialogue*, 27 U.S. 1 (1829).

21. *Egbert v. Lippmann*, 104 U.S. 333 (1881).

22. Teva erroneously argues in its opposition brief that Helsinn's "reading of the AIA would require overruling the *Pennock* line of cases." Opp. Br. at 31.

added) (citing *Elizabeth v. Pavement Co.*, 97 U.S. 126 (1877)). *Egbert* thus at least supports that an imposition of a confidentiality restriction can be an exception to an invalidating sale or use.

More recently, in *Pfaff*,[23] this Court recognized that both the on sale and public use bars of § 102 stem from the same "reluctance to allow an inventor to *remove existing knowledge from public use.*" *See Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1379 (Fed. Cir. 2005) (emphasis added) (quoting *Pfaff*, 525 U.S. at 65). "The patent laws [] seek both to protect the public's right to retain knowledge *already in the public domain* and the inventor's right to control whether and when he may patent his invention." *Pfaff*, 525 U.S. at 65 (emphasis added).

This Court's pre-AIA precedent thus recognized the rationale underlying the on sale and public use bars as resting on the public accessibility to the invention, without confidentiality restrictions.

Teva's own brief acknowledges this Court's recognition of the significance of a "limitation or restriction, or injunction of secrecy." Opp. Br. at 6-7 (quoting *Egbert*, 104 U.S. at 336). In an effort to avoid the clear statutory language of § 102(a)(1), Teva misconstrues *Pennock* and relies on what Teva calls "the leading lower-court case," *Metallizing Engineering Co. v. Kenyon Bearing & Autoparts Co.*, 153 F.2d 516 (2d Cir. 1946)), Opp. Br. at 7, ignoring that that case has been vigorously criticized. *See, e.g.*, D. Karshtedt, *Did Learned Hand Get It Wrong?: The Questionable Patent Forfeiture Rule of Metallizing*

23. *Pfaff v. Wells Elecs.*, 525 U.S. 55 (1998).

*Engineering*, 57 Vill. L. Rev. 261 (2012). Teva's reliance on its characterization of previous case law is inconsistent with the plain language of the statute, its legislative history, the USPTO's interpretation, canons of statutory construction, and this Court's precedent.

The new AIA § 102(a)(1) "on sale" bar explicit requirement that the sale must make the "claimed invention" "available to the public" thus comports with this Court's long-standing recognition of this exceptional circumstance.

Confidentiality has always mattered, and still does. Now, the AIA has expressly and unambiguously incorporated a requirement that "on sale" prior art must make the "claimed invention" "available to the public" in order to fall within the scope of invalidating prior art under § 102(a)(1).

## IV. Conclusion

For the foregoing reasons, the judgment of the U.S. Court of Appeals for the Federal Circuit should be reversed.

Respectfully submitted,

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